BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0092]

Concurrence with OIE Risk Designations for Bovine Spongiform Encephalopathy

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to concur with the World Organization for Animal Health's (OIE) bovine spongiform encephalopathy (BSE) risk designations for seven regions. The OIE recognizes these regions as being of negligible risk for BSE. We are taking this action based on our review of information supporting the OIE's risk designations for these regions.

FOR FURTHER INFORMATION CONTACT: Dr. Roberta Morales, Senior Staff Veterinarian, Regionalization Evaluation Services, National Import Export Services, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7735.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 92 subpart B, "Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard to Bovines" (referred to below as the regulations), set forth the process by which the Animal and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories:

Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status. The list can also be obtained by writing to APHIS at National Import Export Services, 4700 River Road Unit 38, Riverdale, MD 20737.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for countries that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country by the OIE.

If the OIE has recognized a country as either BSE negligible risk or BSE controlled risk, APHIS will seek information to support our concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that countries supply the same information given to the OIE. APHIS will announce in the *Federal Register*, subject to public comment, its intent to concur with an OIE classification.

In accordance with that process, we published a notice[1] in the *Federal Register* on January 23, 2017 (82 FR 7786, Docket No. APHIS-2016-0092), in which we announced our intent to concur with the OIE risk designations for seven regions. The OIE recognizes these regions as being of negligible risk for BSE. We solicited comments on the notice for 60 days ending on March 24, 2017. We received one comment by that date, from a private citizen.

[1] To view the notice and the comment we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0092.

The commenter expressed concern that there is no process for verifying whether ruminant-to-ruminant feed bans are effectively enforced.

As part of its risk assessment process, the OIE considers the likelihood that the BSE agent either could be introduced into or spread within a country through contaminated commodities, including animal feed and feed ingredients. They consider both the production of processed animal proteins from domestic livestock, and the use of imported processed animal proteins, animal feed, and feed ingredients when assessing that risk. APHIS reviews similar information before concurring with the OIE designation.

Once recognized as either negligible or controlled risk for BSE by the OIE, a country must submit data on surveillance results and feed controls for the previous 12 months annually to maintain that status. If a country fails to provide that data in a timely manner, or the data shows changes that increase the risk of BSE introduction or spread, the country's risk designation may be changed. In the event that a country's risk status is demoted by the OIE, APHIS would also change its risk designation for the country.

Within the United States, the Food and Drug Administration (FDA) is the Federal agency responsible for regulating animal feed. The FDA has established regulations in 21 CFR part 589 that prohibit mammalian protein in ruminant feed (which includes a ruminant-to-ruminant feed ban) and the use of tissues that have the highest risk for carrying the BSE agent in all animal feed. These high risk cattle materials, known as specified risk materials (SRM), include the brains and spinal cords from cattle 30 months of age and older.

To assess and monitor for compliance with the feed ban, the FDA established the ruminant feed ban inspection program and guidance to assist both the FDA and State investigators. Feed mill and rendering plant inspections conducted since 1998 indicate a very

high level of compliance with the feed ban. Summaries of inspections can be viewed on the FDA website at https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/ucm114507.htm. The FDA also established a feed testing program in 2001. The FDA's highest priority for sample selection is given to finished products intended for ruminants, and feed ingredients that may reasonably be expected to be later used in ruminant feed.

The commenter also expressed concern that products from cattle slaughtered at 36 months of age pose a health risk to consumers.

The commenter is correct that certain bovine products and live cattle from specific countries with a higher risk of BSE release may carry BSE infectivity and therefore present a health risk to consumers if no measures are taken to mitigate that risk. For this reason, the OIE also describes specific requirements for certain commodities originating from regions of controlled and undetermined risk.

APHIS regulations require implementation of and compliance with very similar requirements for both live bovines and bovine commodities in a region before we concur with the OIE's BSE risk designation. These requirements mitigate the risk of exposure to a negligible level. Therefore, countries with either controlled or undetermined risk statuses must demonstrate that they have the authority to conduct oversight of the compliance with such requirements.

Therefore, in accordance with the regulations in § 92.5, we are announcing our decision to concur with the OIE risk classifications of the following countries:

- Regions of negligible risk for BSE: Costa Rica, Germany, Lithuania, Mexico, Namibia, Romania, and Spain.

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 2nd day of August 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017-16674 Filed: 8/7/2017 8:45 am; Publication Date: 8/8/2017]